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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,037	11/14/2006	Fraser James Buchanan	36290-0425-00-US (229895)	4052

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EXAMINER	
KWAK, JAE J	

ART UNIT	PAPER NUMBER
1796	

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10/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,037	BUCHANAN, FRASER JAMES	
	Examiner	Art Unit	
	JAE KWAK	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 19-48* is/are pending in the application.

4a) Of the above claim(s) *1,19-21,30-33 and 42-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-29 and 34-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/14/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 22-29, and 34-41 in the reply filed on September 8th, 2009 is acknowledged and Groups I, III, and IV, claims 1, 19-21, 30-33, 42-48 are withdrawn as nonelected claims.

Claim Objections

2. Claims 22-29 and 34-41 are objected to because of they depend on withdrawn claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 22-29, and 34-41 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 34 recites the limitation "the molecular weight distribution of the implantable substrate has been altered. This renders claims indefinite because it is unclear as to the nature and degree to which the molecular weight distribution has been altered.

Claims 23 and 35 recites the limitation "a graded molecular weight distribution" in line 2. This is unclear and confusing as to what applicants regard as a "graded molecular weight distribution".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 22, 28-29, and 34, 40-41are rejected under 35 U.S.C. 102(e) as being anticipated by Shalaby (US 2004/0133237).

Regarding claims 22, 29: Shalaby teaches absorbable biomedical devices/implantable substrate such as a surgical suture that degrades polymer coating by controlling exposure to electron beam radiation (Paragraph 4). Shalaby also teaches controlling mass loss of absorbable biomedical devices which changes physical properties (Paragraph 6) by electron beam radiations. It is therefore inherent that the electron bream radiation changes physical properties (i.e. molecular weight) of the polymer, since such a property is evidently dependent upon the nature of the composition used. Case law holds that a material and its properties are inseparable. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Regarding claim 28: Shalaby teaches polymer comprising a high lactide-based polymer/polylactide (Paragraph 8) which reads on the instant claim.

Regarding claims 34, 41: Shalaby teaches absorbable biomedical devices/implantable substrate such as a surgical suture that degrades polymer coating by controlling exposure to electron beam radiation (Paragraph 4). Shalaby also teaches controlling mass loss of absorbable

biomedical devices which changes physical properties (Paragraph 6) by electron beam radiations. It is therefore inherent that the electron bream radiation changes physical properties (i.e. molecular weight) of the polymer, since such a property is evidently dependent upon the nature of the composition used. Case law holds that a material and its properties are inseparable. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Regarding claim 40: Shalaby teaches polymer comprising a high lactide-based polymer/polylactide (Paragraph 8) which reads on the instant claim.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 23, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalaby as applied to claim 22 above, and further in view of Campbell (US 2007/0078513)

Shalaby teach the basic claimed composition as set forth above.

Regarding claims 23, 25-27: Shalaby is silent the thickness of substrates having a graded molecular weight distribution. However, Campbell teaches coating layer/graded molecular distribution of the bioabsorbable polymeric materials such as polycaprolactone/bioabsorbable polymer (Paragraph 24, Claim 7) with different molecular weight layering/molecular distribution such as highest molecular weight polymer closet of implant/core layer, and lower molecular

weight polymer is farthest from the implant/outer surface (Paragraphs 12-13). Shalaby and Campbell are analogous art since they are both concerned with same field of endeavor, namely polymer coated medical devices. At the time of the invention a person having ordinary skill in the art would have found it obvious to combine polymeric materials of Campbell with absorbable biomedical device of Shalaby and would have been motivated to do so for such desirable properties to control degradation rate of the polymeric materials by altering the molecular weights of the polymers, as evidence by Campbell (Paragraph 27)

9. Claims 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shalaby as applied to claim 22 above, and further in view of Roby et al. (US 5,889,075)

Shalaby teach the basic claimed composition as set forth above.

Regarding claim 24: Shalaby is silent on the rate of bioabsorbability of the implant is predetermined. However, Roby et al. teaches treating a surgical suture to enhance its bioabsorbability by exposing radiation which enhanced rate of absorption (Col. 1 line 45, Col. 4 line 55). Shalaby and Roby et al. are analogous art since they are both concerned with same field of endeavor, namely radiating biocompatible medical devices. At the time of the invention a person having ordinary skill in the art would have found it obvious to determine the rate of absorption taught by Roby et al. as absorbable rate for biomedical device of Shalaby and would have been motivated to do so for such desirable properties to fabricating the controlled degradation of the biocompatible device.

10. Claims 35, and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalaby as applied to claim 34 above, and further in view of Campbell (US 2007/0078513)

Shalaby teach the basic claimed composition as set forth above.

Regarding claims 35, 37-39: Shalaby is silent the thickness of substrates having a graded molecular weight distribution. However, Campbell teaches coating layer/graded molecular distribution of the bioabsorbable polymeric materials such as polycaprolactone/ bioabsorbable polymer (Paragraph 24, Claim 7) with different molecular weight layering/molecular distribution such as highest molecular weight polymer closet of implant/core layer, and lower molecular weight polymer is farthest from the implant/outer surface (Paragraphs 12-13). Shalaby and Campbell are analogous art since they are both concerned with same field of endeavor, namely polymer coated medical devices. At the time of the invention a person having ordinary skill in the art would have found it obvious to combine polymeric materials of Campbell with absorbable biomedical device of Shalaby and would have been motivated to do so for such desirable properties to control degradation rate of the polymeric materials by altering the molecular weights of the polymers, as evidence by Campbell (Paragraph 27).

11. Claims 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shalaby as applied to claim 34 above, and further in view of Roby et al. (US 5,889,075)

Shalaby teach the basic claimed composition as set forth above.

Regarding claim 36: Shalaby is silent on the rate of bioabsorbability of the implant is predetermined. However, Roby et al. teaches treating a surgical suture to enhance its bioabsorbability by exposing radiation which enhanced rate of absorption (Col. 1 line 45, Col. 4

line 55) Shalaby and Roby et al. are analogous art since they are both concerned with same field of endeavor, namely radiating biocompatible medical devices. At the time of the invention a person having ordinary skill in the art would have found it obvious to determine the rate of absorption taught by Roby et al. as absorbable rate for biomedical device of Shalaby and would have been motivated to do so for such desirable properties to fabricating the controlled degradation of the biocompatible device.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAE KWAK whose telephone number is (571)270-7339. The examiner can normally be reached on Monday to Friday 8:30 A.M. EST 5:30 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

J.K.

/Anthony McFarlane/